



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,237	11/13/2006	Wei Wu	13589.0002	3671

7590 11/14/2007  
Kirton & McConkie  
1800 Eagle Gate Tower  
60 East South Temple  
Salt Lake City, UT 84145-0120

EXAMINER
----------

ROZANSKI, MICHAEL T

ART UNIT	PAPER NUMBER
----------	--------------

3768

MAIL DATE	DELIVERY MODE
-----------	---------------

11/14/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/556,237

Applicant(s)

WU, WEI

Examiner

Michael Rozanski

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-42 is/are pending in the application.
- 4a) Of the above claim(s) 39-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/22/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group IV (claims 25-33) in the reply filed on 9/14/07 is acknowledged. Traversal is on the grounds that the Office has not substantiated that restriction between the claims as categorized is warranted. Upon further consideration, Examiner regards Groups I-V as being drawn to a common invention, wherein there would not be a serious burden to examine all groups. However, Examiner maintains that Group VI (claims 39-42) would require a further search not required by the limitations in Groups I-V, as claim 39 features an ultrasonic treatment head. This treatment head features limitations not required in the ultrasonic treating portion or the irradiation steps in Groups I-V.

Claims 39-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected apparatus, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/14/07.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3768

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims **15-16, 21, 23, 25-28, 34-36, and 38** are rejected under 35 U.S.C. 102(e) as being anticipated by **Mangin** (US Pub 2003/0206864).

Mangin discloses providing embolic particles for effecting embolization, which particles comprise one or more voids for containing microbubbles such that the particle is visible under ultrasound (para [0025]) and is introduced by injection with a positioning portion (para [0110, 0117]). The embolic particle may be of various sizes wherein a size large enough would cause embolization (para [0030]). The invention also provides methods of treatment of cancer and reducing the size of a tumor (para [0006]). The microbubble generating ultrasound contrast agent may be Albunex, which has CO<sub>2</sub> filled microbubbles and a shell that contains Human Serum Albumin (para [0051]). Further, the CO<sub>2</sub> based agent containing a compatible carrier [0050] is produced by a procedure in which an aqueous soluble material is suspended in a polymer solution (para 0037)).

In addition, it is noted that irradiating the reagent with ultrasound in an area where embolus is desired to be formed does not require that the ultrasound causes the embolus. However, while Mangin teach that the embolic particle is visible under ultrasound, irradiating the particles would inherently cause, or at least increase the rate of formation, embolus as described in claims 16, 21, and 23.

Art Unit: 3768

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims **17-20, 22, 24, and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Mangin*** (US Pub 2003/0206864).

**Mangin** substantially disclose all features of the current invention but does not specifically describe the claimed irradiation frequency and timing or the reagent dosage. However, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have used routine experimentation by selecting different frequencies, irradiation timing, and dosage to determine optimum operating parameter in order to make the embolization process efficient and effective.

6. Claims **29-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Mangin*** as applied to claim 26 above, and further in view of ***Feril*** (Dose-dependent inhibition of ultrasound-induced cell killing and free radical production by carbon dioxide; Ultrasonics Sonochemistry 10(2003) 81 84).

**Mangin** substantially disclose all features of the current invention but does not specifically mention producing the CO<sub>2</sub> based reagent by reacting an organic acid and NaHCO<sub>3</sub>. In the same field of endeavor, **Feril** teaches of reacting HCl and NaHCO<sub>3</sub> to produce a predictable concentration of CO<sub>2</sub> within a medium (see 1. Introduction). It

Art Unit: 3768

would have been obvious to one with ordinary skill in the art at the time the invention was made to have produced CO<sub>2</sub> according to the teaching of Feril when making the reagent of Mangin because Feril teaches one known manner of producing CO<sub>2</sub> microbubbles at a known concentration and Mangin requires microbubbles.

7. Claims **31-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mangin** as applied to claim 25 above, and further in view of **Kung** (6,241,963).

Mangin substantially disclose all features of the current invention but does not specifically describe a marking or tracing isotope combined with a targeting substance as claimed. However, Kung teaches of such targeting substances (i.e. <sup>99m</sup>Tc, <sup>123</sup>I) that can be used with a tracing isotope (col 16, line 63-col 17, line 17). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify Mangin to include a tracing isotope as taught by Kung, since this allows determining where the isotope is delivered.

### **Conclusion**

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

Art Unit: 3768

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MR  
MR

ERIC F. WINAKUR  
PRIMARY EXAMINER